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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/529,613 | 06/08/2005 | Sridhar Kudaravalli | 4-32702A | 1738 |
| 1095 NOVARTIS | 7590 11/17/200 | 9 | EXAMINER | |
| | INTELLECTUAL PROPE | OPERTY | POHNERT, STEVEN C | |
| ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Attachment to Advisory

Continuation of box 11:

The amendment has been entered but has not the pending claims in condition for allowance.

The amended claims would thus be subject to a scope of enablement rejection as the claims broadly encompass any degree of elevation in any type of cholesterol. The claim has changed the scope from determining the degree of serum cholesterol elevation to determining predisposition to cholesterol elevation, thus changing the scope of the claimed invention. Table 5 teaches that total cholesterol is increased regardless of genotype at IL-1β position -31 with everolimus treatment. Table 7 teaches that there is a statistically significant increased in LDL in all subjects with everolimus treatment regardless of IL-1β position -31 genotype. Tables 9 demonstrate there are no significant differences in HDL cholesterol levels regardless of genotype at IL-1β position -31. Thus the claims are not predictably associated with "any" elevation in "any" type of cholesterol as LDL does not appear to be predictably associated with IL-1β position -31. Thus as the scope of enablement rejection clearly indicated the level of elevation of serum cholesterol is required to allow the artisan to predictably to practice the invention as claimed.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-

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3803. The examiner can normally be reached on Monday-Friday 7:00-:4:30, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven C Pohnert/ Examiner, Art Unit 1634

Steven Pohnert